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ORIGINAL ARTICLE

Clinical Assessment of a Customized Free-Form Progressive Add Lens Spectacle

Susan C. Han*, Andrew D. Graham†, and Meng C. Lin‡

ABSTRACT

Purpose. To determine whether there are significant differences in standard clinical measures of vision, progressive addition lens (PAL)-specific vision tests, or subjective ratings and preferences between customized free-form and standard non-free-form PALs in an experienced wearing population. In addition, we aim to determine whether subjective or objective clinical outcomes depend on demographic, PAL usage, spectacle prescription, or frame fitting characteristics.

Methods. In a randomized, double-masked cross-over trial, 95 experienced wearers wore Zeiss Individual customized free-form PAL spectacles (test) and standard non-free-form PAL spectacles (control) for 1 week each. At dispensing and after 1 week of wear, subjects were tested for distance and near visual acuity under both high and low contrast; in addition, 30° off-axis visual acuity was measured using a novel apparatus, as was the horizontal extent of clear, undistorted vision at reading distance. Subjects also completed a set of questionnaires detailing their satisfaction levels, adaptation times, and preferences for test or control spectacles for different visual tasks.

Results. The test spectacles were preferred overall and for distance, midrange, transitional and active vision, and rated higher in overall satisfaction ($p = 0.006$). There were no clinically important differences between test and control spectacles in standard clinical vision assessments. In the PAL-specific assessments, however, the horizontal extent of clear vision at reading distance was significantly greater with the test spectacles ($p = 0.004$).

Conclusions. There were statistically significant preferences for the optically customized free-form lenses over the non-free-form lenses. Subjects also reported a wider field of undistorted vision when looking through the reading zone of the test spectacles. Although standard clinical vision assessments are not sufficiently refined to detect important objective differences between the spectacle types, customization taking into account back vertex distance, segment height, pantoscopic tilt, and wrap angle can result in a superior subjective wearing experience for many PAL patients. (Optom Vis Sci 2011;88:234–243)

Key Words: progressive addition lenses, customized free-form, presbyopia, bifocals, subjective assessment, visual performance, visual acuity, Amsler grid

Progressive addition lenses (PALs) offer several advantages over-lined bifocal or multifocal lenses, including the continuous transition in addition power from a zone focused for distance vision in the upper region of the lens to a near vision zone in the lower part of the lens, without visible lines of demarcation. Previous studies have compared patients' satisfaction with progressive lenses to that with other types of presbyopic correction and found that the majority of subjects preferred progressive lenses.[1–3] Nevertheless, progressive lenses still prove difficult for some patients to adapt to, and many patients prefer to remove their PAL spectacles for certain tasks, suggesting the potential for an improved clinical outcome. In one study that examined the various types of corrections for presbyopia, progressive lens wearers were more satisfied than bifocal lens wearers with driving, and yet PAL wearers also reported distortion of their peripheral vision.[4] Progressive surfaces produce a smooth, continuous change in addition power by "blending" the peripheral regions of the lens surface through the use of surface astigmatism. Significant surface astigmatism results in unwanted blur, image distortion, and a sensation of motion, swim or vertigo, particularly when transitioning abruptly to focus at different distances, or when viewing the environment through the aberrated periphery of the lens. Although this inherent surface astigmatism is generally minimized to its mathematical limits in modern progressive lens designs, traditional progressive lenses still suffer from the optical compromises of mass

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lens production, which commonly relies on making a relatively small number of unique lens designs work sufficiently well for a large population of wearers with diverse visual requirements. These optical compromises can exacerbate the unwanted astigmatism effects of the progressive lens by introducing additional focusing errors, reducing the overall satisfaction level of the patient, and preventing some patients from adjusting to the lenses.

The use of a limited number of base curves or unique optical designs also results in residual optical aberrations in the periphery of the lens.[5] The position of the fitted spectacles can introduce additional prescription errors through both the central and peripheral regions of the lens because of the effects of lens tilt.[6] These residual optical aberrations are particularly problematic with progressive lenses because oblique astigmatism interacts with the surface astigmatism inherent in the lens design, resulting in narrower and often distorted viewing zones. Because of the mathematical constraints of progressive surfaces, the use of only one or two corridor lengths results in either unnecessarily narrow viewing zones if the corridor is longer than necessary or insufficient reading utility if the corridor is shorter than necessary.[7] Traditional manufacturing relies on a mass production process in which a small number of initial progressive lens designs are optically optimized for relatively broad categories of wearers by assuming an average prescription power, fitting geometry, and frame size for each lens design. Uncorrected optical aberrations therefore occur in the final lens as a result of differences between the actual prescription or position of wear and the values assumed during the calculation process. Because traditional lens surfacing is limited to basic spherical and spherocylindrical (toric) lens surfaces, no further optical optimization can be applied.

Recent breakthroughs in the lens manufacturing process have created the opportunity for lens manufacturers to further minimize these optical aberrations, with the desired effect of improving patient acceptance and satisfaction.[8] Manufacturers have begun introducing progressive lenses with one or both surfaces fabricated using a free-form surfacing process, which can produce surfaces of significantly greater complexity. Although free-form surfacing can be used to manufacture traditional progressive lenses, it is also being used in conjunction with advanced optical design software to produce a surface that modifies the initial lens design based on the specific visual requirements of each wearer. The software uses the fitting characteristics of the frame on the patient in creating individually customized free-form progressive lenses. PAL spectacles can be customized by incorporating the wearer's individual vertex distance, pantoscopic tilt, frame wrap, and frame size measurements during the optical optimization process to reduce aberrations caused by the specific prescription and fit of the spectacles on the patient. It is thought that customized lens designs delivered via free-form PAL processing could lead to improvements such as wider distance/intermediate/reading areas, reduced blur, and increased image sharpness.[8]

Studies have been conducted to determine whether various progressive lens designs outperform others. For example, the study of Borish and the VEPRO trial compared newer progressive lenses to older designs, in randomized cross-over trials.[9,10] To our knowledge, however, there has not been a randomized cross-over trial comparing customized free-form progressives to traditional (non-free-form) progressives to date. In this study, we compare lenses which are optically customized for each wearer's prescription requirements, position of wear, and frame size before fabrication using free-form lens surfacing to traditional PALs, which are fabricated from a factory-molded progressive lens blank using traditional lens surfacing with a conventional spherocylindrical (toric) surface. In this study, we aim to determine whether there are significant differences in standard clinical measures of vision, PAL-specific vision tests, and/or subjective ratings and preferences between customized free-form and standard progressive lenses in an experienced PAL wearing population. In addition, we aim to determine whether objective or subjective clinical outcomes depend on demographic, PAL usage, spectacle prescription, or frame fitting characteristics.

METHODS

Study Design

This study was a randomized, double-masked cross-over trial comparing a customized free-form progressive lens spectacle to standard non-free-form progressive lens spectacles in an experienced PAL wearing population. Subjects wore test and control spectacles for 1 week each, and completed clinical vision assessments and questionnaires at baseline and after 1 week of wear of each pair of study spectacles. The order of wear of the test and control spectacles was randomized, and the subjects, the optometrists, and the technicians administering any measurements or questionnaires were masked as to which type of spectacle was being worn at each visit.

Subject Recruitment

Presbyopic subjects were recruited from the population of patients who were purchasing non-free-form PAL spectacles with antireflective coating in new frames from the University of California, Berkeley School of Optometry Eyewear Center. Subjects were all experienced progressive lens wearers. Subjects purchasing free-form PALs were excluded from participation. The sample size required for this study was not formally estimated; 100 subjects were requested by the trial sponsor based on their own preliminary data. After designing all aspects of the trial, we performed a pilot run of 13 subjects to ensure that all questionnaire and laboratory data could be collected on 100 subjects within the time frame of the trial. On the basis of the data from sponsor and our pilot, we determined that a sample size of 100 subjects would be more than sufficient to detect any clinically meaningful differences should they exist. In post hoc testing, we determined that the 95 subjects completed would allow us to detect ~a 0.02 logarithm of the minimum angle of resolution (logMAR) difference between spectacles with 95% confidence and 80% power. On selection of PAL spectacles and frames, potential subjects were referred to the University of California, Berkeley Clinical Research Center, where they were informed about the trial. Subjects expressing interest in participating, had their examination records sent to the Clinical Research Center, where they were verified to ensure that the subjects were correctable to at least 20/25 in both eyes and did not have any eye conditions or diseases that could potentially cause a decrease in visual acuity (VA) during the course of their participa-

tion in the study or affect their ability to use PALs as their primary form of vision correction.

Test and Control Spectacles

The test spectacles used were Zeiss Individual, fitted using the i.Terminal (Carl Zeiss Vision, Germany). The i.Terminal is a digital video centration device that automatically measures various fitting characteristics for the individual subject and chosen frame, including frame wrap angle, pantoscopic tilt, and back vertex distance, that are not part of the standard fitting parameters for PAL spectacles. Subjects were required to have prescriptions within the ranges of lenses and materials available for the Zeiss Individual. Available materials included CR39 (allyl diglycol carbonate, PPG Industries, Pittsburgh, PA), polycarbonate and 1.67 (high index plastic), available in clear or photochromic (gray or brown). For the CR39 material, available sphere powers ranged from +5.0 diopters (D) to −6.0 D, with add powers from +0.75 D to +3.5 D for clear lenses, and to +3.0 D for photochromic lenses. The polycarbonate and 1.67 materials ranged in sphere power from +6.0 D to −10.0 D, with available add powers ranging from +0.75 D to +3.5 D for polycarbonate, and to +3.0 D for the high index material. Maximum cylinder power for all lenses was −4.0 D.

The non-free-form control pair was chosen by the subject at the Eyewear Center, before being informed about the study, from a variety of popular PAL brands after considering a combination of factors, including prior PAL wearing history and recommendations from the fitting optician and optometric clinician according to standard practice. The non-free-form PAL brands included Solamax, AO Compact, Hoyalux Summit, Kodak Concise, Kodak Precise, Ovation, Proceed, Comfort Ellipse, Panamix, GT2, Varilux Physio, and Gradal Top. The final distribution of PAL brands across subjects was similar to the distribution of these brands among all patients of the Eyewear Center. The test and control spectacles were manufactured with identical prescriptions, monocular pupillary distances, segment heights, lens materials, frames, and antireflective coating. To adhere to the standard PAL spectacle fitting practices of dispensing opticians, the pupillary distance was measured using an automated pupillometer, and segment height was measured manually. The two pairs of study spectacles differed in base design, free-form surfacing of the test lenses, and the additional optical customization of the test lenses based on individual prescription, frame size, and i.Terminal measurements. American Board of Opticianry-certified opticians who were trained and certified by the Clinical Research Center to operate the i.Terminal used this instrument to measure the additional fitting parameters, which included pantoscopic tilt, back vertex distance, and frame wrap angle. These additional measurements were supplied only to the laboratory manufacturing the test lenses. Both pairs of study spectacles were verified on receipt to ensure that they had been manufactured correctly.

Before initiating recruitment for the main trial, we conducted a repeatability and reproducibility study of the spectacle fitting parameters generated by our opticians. After a sufficient period of optician training on the i.Terminal, three volunteer subjects wearing test frames had fitting measurements taken by the five opticians involved in the trial, in random order, which were repeated on the following day. We constructed limits of agreement, examined difference-vs.-means and a variety of other plots, and conducted variance component analyses, to ensure that our manual pupillary distance and segment height measurements, and the back vertex distance, pantoscopic tilt, and frame wrap angle generated by the i.Terminal were repeatable and reproducible.

All subjects were oriented as to the goals, risks, and benefits of the study before signing a consent form. Subjects paid for their Control lenses and frames as normal in the Eyewear Center, before being informed about the study. Subjects who were eligible and elected to participate in the trial were compensated at the end of the trial with the Zeiss Individual lenses in an identical frame and a $50.00 gift certificate for the University of California, Berkeley School of Optometry Clinic. This study adhered to the tenets of the Declaration of Helsinki and was approved by institutional review board. In accordance with the recommendations of the International Committee of Medical Journal Editors, we have registered this clinical trial (URL: www.clinicaltrials.gov).

Standard Clinical Assessments of Vision

Distance visual acuities under both high (~100%) and low (~10%) contrast were measured using the M&S Technologies (Dallas, TX) Smart System two projection system. The M&S Technologies system is a computerized vision testing system based on the Early Treatment Diabetic Retinopathy Study (ETDRS) letter set, with a logarithmic progression of equally spaced rows separated by 0.1 log units. For letters that are 20/63 and smaller, there are five letters per row; for letters 20/80 and greater, the number of letters per row changes because of the limits of screen size. This electronic ETDRS protocol was approved by Food and Drug Administration for use in clinical trials and has the advantage that presentation of letters can be randomized to prevent subjects from memorizing the chart from one visit to the next. Binocular near VA was measured at 40 cm using ETDRS near charts in both high and low contrast. We used multiple versions of the near charts so that patients could not memorize the letters on the charts from one visit to the next. VA was recorded as logMAR.

Novel PAL-Specific Assessments of Vision

An apparatus was created specifically for this study. It consisted of a forehead and chin rest securely mounted on an adjustable testing table. For each subject, the apparatus was adjusted for maximum head stability and immobilization, while maintaining acceptable subject posture and comfort. Adjustment parameters included the height of apparatus from the floor, chin rest height, positions of right and left temple stabilizing pads, and the vertical and transverse distances and viewing angle of the reading surface, all of which were adjusted individually for each subject to achieve a normal and comfortable posture. Adjustment parameters were recorded at the first visit for each subject, and the apparatus was reset to these same parameter values for all subsequent visits. The apparatus was used for distance VA under high and low contrast using the ETDRS charts at viewing positions 30° off axis to the right and left sides. Multiple versions of the ETDRS charts were used so that subjects could not memorize the letters on the charts from one visit to the next. For off-axis viewing, subjects were monitored to ensure that their heads remained immobilized in the

on-axis position, and that they could move only their eyes to view the ETDRS charts from 30° to the periphery.

The testing apparatus was also used to measure the horizontal extent of undistorted near vision, which was assessed using a modified grid, similar to the Amsler grid, which had been elongated to a width of 60 cm and a height of 10 cm, with 1 point thickness black lines spaced at 0.5 cm. Extensive preliminary testing was done to determine the optimal width, height, line thickness and spacing, line and background colors, and central reference marking for PAL-wearing volunteers to most easily and reliably indicate the point at which peripheral viewing became aberrated. Subjects were positioned in the apparatus as described above and could then move only their eyes to the right and left sides to indicate with a finger the extent of undistorted vision at reading distance through the near zone of the PAL spectacles, which was recorded by a technician from a numerical scale printed along the grid edge where it was not visible to the subject. The ambient light condition was kept constant for all visits.

Questionnaires

Questionnaires asking subjects to rate each pair of spectacles on a 0 to 100 scale (100 = excellent overall satisfaction), to indicate how long it took to adapt to each pair, and to give a strength of preference for the test or control spectacles on a 6-point forced choice Likert scale, were administered at each visit. Subjects were masked as to which were the randomly assigned test and control pairs, which were referred to on questionnaires only as study pair 1 and study pair 2. In addition, a final exit questionnaire asked the subjects to choose one pair of spectacles or the other as their preference for distance, midrange, and near vision, as well as for transitional visual tasks, active vision, and overall preference. Results from these commonly used types of rating and preference questionnaires are presented in this article.

In addition to the questionnaires described above, a novel questionnaire instrument was designed, using Rasch analysis, to assess the subjective visual experience with PALs. This lengthy questionnaire assessed subjects' visual quality, visual comfort and awareness of their lenses at varying distances, under different viewing conditions, and for a wide array of visual tasks. A complete description of this questionnaire, the Rasch analysis, and final outcomes will be presented in a subsequent article.

Study Protocol

Three visits were required for all subjects. Subject recruitment as well as initial fitting and dispensing of both pairs of spectacles were conducted by certified opticians in the Eyewear Center. The other objective and subjective clinical measures as described above were conducted by Clinical Research Center optometrists and staff. The initial/screening visit included the selection of new glasses, recruitment for the study, and signing of the consent form. Once consent was obtained, the research optometrist confirmed subject eligibility for the study and the test spectacle orders were processed. Once both pairs of spectacles had been received, the three main study visits were scheduled. At visit 1, subjects completed a questionnaire regarding their habitual spectacles. Pair 1 spectacles (test or control, according to the randomization assignment) were dispensed and all the standard clinical test data and novel PAL-specific test data (discussed above) were collected. At visit 2, the same battery of tests was repeated for pair 1 after 1 week of wear. The subject then returned pair 1 and received pair 2. The same tests were conducted for pair 2. At visit 3, the same sequence of tests was conducted for pair 2 after 1 week of wear. On exiting the study, subjects were asked to choose the best pair of spectacles for several different viewing distances and tasks. They were given both pairs of spectacles, marked only as pair 1 and pair 2, so they could refresh their memories of their wearing experiences.

Statistical Analysis

Data were first subjected to an exploratory data analysis, in which descriptive statistics were calculated, paired t-tests were performed, and a variety of plots of the data were examined to screen for data entry errors or other outliers. Mixed effects multivariate models were then fit, with a single random effect to account for the correlation between eyes within subjects, and fixed effects for the independent variables including demographics, PAL usage, spectacle prescription, and frame fitting characteristics. Final models were chosen based on estimated effect sizes, F-test p-values, Aikake's Information Criterion and other model diagnostics, and examination of residual and fitted value plots. All p-values reported below are from the multivariate linear mixed effects analysis of variance models unless otherwise noted.

RESULTS

We first conducted a preliminary analysis to ensure that both our manual and i.Terminal fitting parameters were repeatable and reproducible. We found that manual pupillary distance and segment height were highly repeatable, with a mean difference between repeated measurements of pupillary distance of 0.10 mm [95% Limits of Agreement (−0.74 to 0.94)], and a mean difference between repeated measurements of segment height of 0.26 mm [95% Limits of Agreement (−1.57 to 2.08)]. We also found that the five opticians maintained good agreement in their pupillometer and manual segment height measurements on individual subjects. The back vertex distance, pantoscopic tilt, and frame wrap angle as measured by i.Terminal also showed repeatability and reproducibility well within the ranges that would not make any noticeable difference to the subjects in vision or wearing comfort. There were no patterns of the differences between repeated measurements being related to their means, and the variability in the data because of repeated measurements and interobserver differences was a very small fraction of the total variance. From this initial validation study, we concluded that our fitting parameter measurements were highly repeatable and reproducible, and that the new i.Terminal measurements would not introduce unwanted variability in our outcome measures.

Ninety-five subjects were recruited and completed the trial. Subjects were typical of the PAL-wearing population of the U.C. Berkeley campus and surrounding community from which we sampled. Subject's age ranged in from 39 to 80 years, with a median age of 58 years. There were 57 females and 38 males, and all except one subject had at least 2 years of postsecondary education. Subjects were 77% white, 14% Asian, and 9% other ethnicities.

TABLE 1.
Prescription and fitting characteristics

	Eye[a]	Minimum	Maximum	Median	Mean	SD
Sphere	OD	−8.00	+5.75	−0.25	−1.22	2.99
	OS	−8.25	+5.25	−1.00	−1.24	2.93
Cylinder	OD	−3.50	0.00	−0.75	−0.87	0.78
	OS	−3.50	0.00	−0.75	−0.90	0.75
Add power	OD	+1.00	+3.00	+2.25	+2.25	0.34
	OS	+1.00	+3.00	+2.25	+2.25	0.34
Segment height	OD	15.0	31.0	20.0	20.3	2.7
	OS	15.0	31.0	20.0	20.4	2.7
Pupillary distance	OD	27.0	36.0	31.0	31.2	2.0
	OS	26.0	35.0	31.5	31.4	2.0
Back vertex distance		9.2	24.7	14.2	14.3	2.8
Pantoscopic angle		0.0	21.2	9.0	10.0	4.8
Wrap angle		1.2	15.0	7.3	7.5	3.4

Lens powers, segment height, and pupillary distance were taken using standard clinical methods. Back vertex distance, pantoscopic angle, and wrap angle were taken using the i.Terminal and applied to the manufacture of the test spectacles only.

[a]Back vertex distance, pantoscopic angle, and wrap angle are characteristics of the frame fit on the subject and are not eye specific.

TABLE 2.
Standard clinical vision assessments

	At fitting			After 1 week of wear		
	Control Mean (SD)	Test Mean (SD)	p	Control Mean (SD)	Test Mean (SD)	p
Distance VA, HC (projector)	−0.11 (0.07)	−0.12 (0.06)	0.213	−0.12 (0.06)	−0.11 (0.07)	0.622
Distance VA, LC (projector)	0.01 (0.09)	0.01 (0.08)	0.705	0.01 (0.07)	0.01 (0.07)	0.425
Distance VA, HC (4m chart)	−0.08 (0.09)	−0.10 (0.14)	0.324	−0.11 (0.13)	−0.09 (0.09)	0.094
Distance VA, LC (4m chart)	0.05 (0.09)	0.06 (0.09)	0.275	0.05 (0.09)	0.12 (0.64)	0.293
Near VA, HC	−0.03 (0.09)	−0.03 (0.10)	0.886	−0.04 (0.09)	−0.03 (0.09)	0.250
Near VA, LC	0.15 (0.09)	0.15 (0.09)	0.715	0.13 (0.09)	0.15 (0.08)	**0.023**

At-fitting tests were taken immediately after dispensing. Control and test measurements were compared in this Table by paired t test. Only near VA under low contrast was significantly different between spectacle types; however, with a mean difference of 0.02 logMAR (~1 letter on the chart), the difference was not of clinical importance.

HC, high contrast; LC, low contrast.

PAL wearing history ranged from 1 to 25 years, with an average of ~10 years. Nearly, all subjects wore their PAL spectacles on a daily basis, for a median time of 13 h/d. Subjects averaged ~4 h/d computer usage, 2 h/d reading, and 1 h/d driving. Spectacle prescription and fitting parameters are shown in Table 1.

Objective Findings

There were few differences between test and control spectacles in any of the standard clinical vision assessments (Table 2). Distance VA under both high and low contrast, and near acuity under high contrast were essentially the same, on average, for both spectacle types, even after adjusting for any potential confounders. Despite the fact that different subjects viewed the near chart through slightly different parts of the lens (e.g., center of reading zone; lower part of transition corridor) as a result of differing add powers and a fixed 40 cm viewing distance; add power was not significantly related near VA.

Near VA under low contrast after 1 week of wear was found to be significantly associated with spectacle type ($p = 0.015$), along with prescription sphere ($p = 0.011$), subject age ($p = 0.002$), and significant or near-significant interactions between spectacle type and hours per day of PAL wear ($p = 0.006$) and brand of control spectacles ($p = 0.052$). Overall, younger subjects with lower sphere power (between −4 D and +3 D) prescriptions had better low contrast near acuity. Although overall (i.e., unadjusted for any other covariates), the control lenses performed marginally better in near low contrast acuity (Table 2), the multivariate model suggests that for subjects who wore their PAL spectacles on a continuous basis (e.g., 19 h/d, the maximum we observed in our subjects), the test spectacles performed better than the controls, but to a degree that was of marginal clinical relevance. Depending on the specific brand or brands of control spectacles compared, the improvement in low contrast near VA with the test spectacles ranged from 0.02 to 0.05 logMAR (~1 to 3 letters on the VA chart).

TABLE 3.
PAL-specific clinical vision assessments

	At fitting			After 1 week of wear		
	Control Mean (SD)	Test Mean (SD)	p	Control Mean (SD)	Test Mean (SD)	p
Distance VA, HC, off-axis left	0.10 (0.12)	0.10 (0.12)	0.802	0.10 (0.13)	0.10 (0.14)	0.861
Distance VA, HC, off-axis right	0.06 (0.11)	0.06 (0.11)	0.805	0.05 (0.09)	0.04 (0.10)	0.120
Distance VA, LC, off-axis left	0.24 (0.10)	0.24 (0.11)	0.663	0.24 (0.12)	0.24 (0.12)	0.816
Distance VA, LC, off-axis right	0.19 (0.11)	0.19 (0.12)	0.986	0.19 (0.10)	0.16 (0.11)	**0.002**
Near vision horizontal extent (cm)	20.03 (11.02)	19.19 (11.16)	0.264	17.74 (9.87)	20.06 (11.89)	**0.004**

At-fitting tests were taken immediately after dispensing. Control and test measurements were compared in this Table by paired t test. Distance VA off-axis (right side) under low contrast was significantly different between spectacle types; however, with a mean difference of 0.03 logMAR (~1 letter on the chart), the difference was not of clinical importance. The horizontal extent of clear vision at reading distance was significantly wider with the test lenses after 1 week of wear.

HC, high contrast; LC, low contrast.

Differences in visual performance between test and control spectacles were somewhat more apparent in the novel assessments designed specifically for this PAL trial (Table 3). After 1 week of wear, distance VA assessed under low contrast at 30° off axis (right side only; see Discussion) was significantly related to spectacle type ($p = 0.002$), along with prescription sphere ($p = 0.001$), cylinder power ($p = 0.025$), standard tilt ($p = 0.021$), subject age ($p = 0.016$), and a near-significant interaction between spectacle type and back vertex distance ($p = 0.055$). Overall, younger subjects with low sphere and cylinder power prescriptions and less frame tilt had better low contrast distance VA when gazing 30° off axis through the periphery of the lenses. Significant and potentially clinically important differences between test and control spectacles (0.073 logMAR, or ~¾ of a line on the VA chart) were found for subjects fitted with shorter back vertex distances (e.g., 9.2 mm, the smallest observed in our sample).

The most apparent objective difference between the test and control spectacles was in the horizontal extent of undistorted vision at reading distance, as measured by the modified Amsler grid after 1 week of wear. The horizontal extent of undistorted near vision was significantly related to spectacle type ($p = 0.003$), along with prescription sphere ($p = 0.034$), years of PAL wear ($p = 0.047$), and significant or near-significant interactions between spectacle type and segment height ($p = 0.064$), and gender ($p = 0.041$). Overall, subjects with fewer years of PAL wear had wider fields of undistorted vision at reading distance. These subjects are, on average, younger and tended to have lower power prescriptions and lower addition power. For subjects with segment heights in the lower end of our fitting range (e.g., below 16 mm), both males and females found the test spectacles to provide a wider undistorted field at reading distance, with males finding the field ~6 cm wider on average with the test spectacles, and females finding the field ~3.5 cm wider. This is most likely due to gender acting as a confounder, because there is no reason to expect females naturally to have a more restricted near field on average compared with males. In univariate unpaired t-tests, gender was significantly related to the width of the field ($p = 0.003$), as was addition power ($p = 0.020$), and female subjects had an average of 0.12 D greater addition power ($p = 0.021$). According to the model, there is minimal difference (<1.6 cm) between test and control spectacles for subjects with the median segment height we observed (20 mm), whereas the control spectacles are estimated to have a wider near field for those fit at the maximum segment height (31 mm).

Although there was no significant difference between test and control spectacles at dispensing, after adapting to the spectacles for 1 week, 58% of subjects found the test spectacles to have a wider extent of undistorted near vision, compared with 33% who found control spectacles to have a wider field, whereas 9% of subjects found no difference between spectacles (Fig. 1). Ethnicity, education level, days per week of PAL wear, amount of driving, reading or computer usage, and pupillary distance were not significantly related to any of the objective clinical outcome measures.

Subjective Findings

Despite there being few objective differences of clinical importance between test and control spectacles, there were significant differences in subjects' questionnaire responses. In a direct preference comparison after wearing each pair of spectacles for 1 week, test spectacles were significantly preferred ($p < 0.001$), after accounting for the effects of cylinder power ($p = 0.003$), control spectacle brand ($p = 0.002$), hours per day of PAL usage ($p = 0.010$), and back vertex distance ($p = 0.007$). For subjects with spherical or near-spherical prescriptions (≤1.5 D of cylinder), the preference for the test spectacles was strongest among subjects fit with a medium back vertex distance (>11 mm and <17 mm) and wearing non-Zeiss control spectacles and was stronger for subjects wearing their PAL spectacles for a fewer number of hours per day. These subjects rated the test spectacles an estimated 1.2 units higher than the controls on our 6-unit Likert scale. Among subjects with prescriptions for astigmatism (>1.5 D of cylinder), there was a much stronger preference for the test spectacles. For subjects wearing non-Zeiss control spectacles, the test spectacles were preferred for all back vertex distances and wearing times. For subjects wearing other Zeiss control spectacles, the test spectacles were preferred for those wearing their PAL spectacles for fewer than the median number of hours per day and were more strongly preferred for those fit with medium back vertex distance. These subjects rated the test spectacles an estimated 2.0 units higher than the controls on our 6-unit Likert scale.

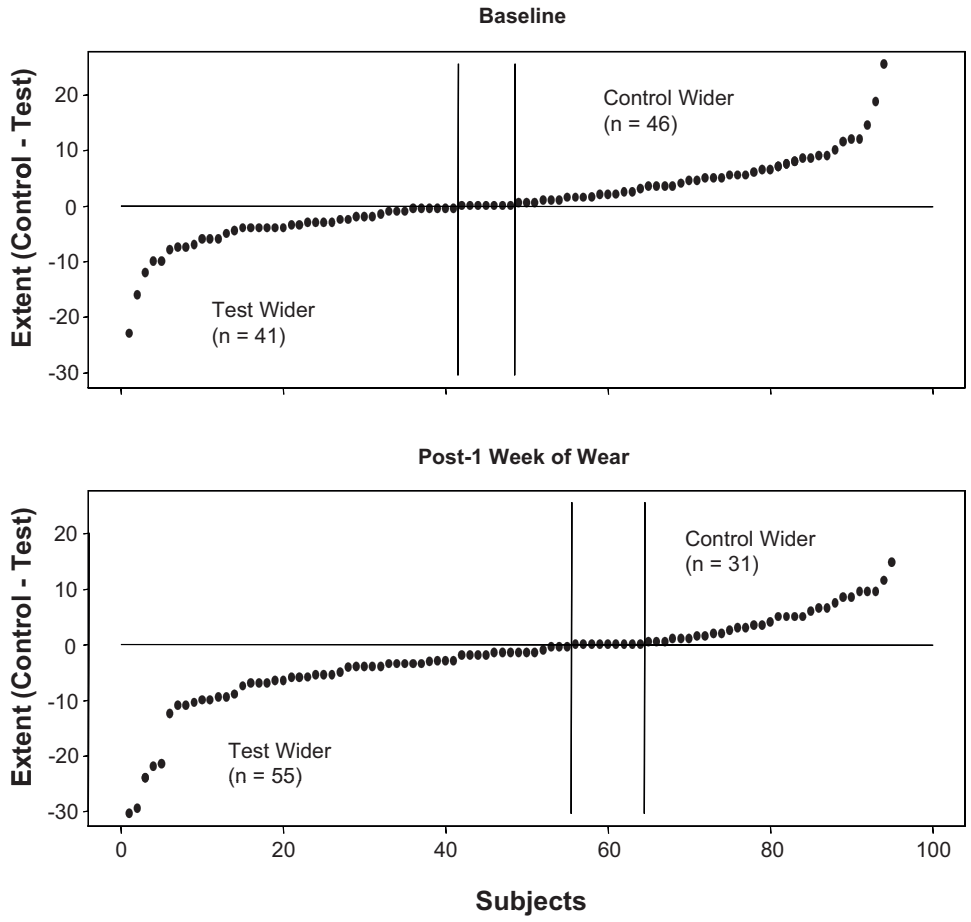

FIGURE 1.

Horizontal extent of undistorted vision at reading distance. Shown in the Figure are the differences (control − test) in extent for each subject. The vertical lines demark those subjects who found the control and test spectacles to have exactly the same extent. At baseline, there was little difference between test and control. After adapting to the spectacles for 1 week, a much greater percentage of subjects reported a wider undistorted near zone with the test spectacles.

Subjects were also asked a series of forced choice preference questions for specific viewing distances and modes of PAL usage. The test spectacles were preferred overall (55% for test vs. 45% for controls). The test spectacles were also preferred for distance vision and for active vision (60% for test vs. 40% for controls, in each case), and for midrange and transitional vision (55% for test vs. 45% for controls, in each case). Subjects indicated no clear preference for near vision (~50% for test and 50% for controls).

Subjects found the test spectacles to have a significantly shorter adaptation time ($p = 0.001$) compared with control spectacles, taking into account significant or near-significant differences in the distance from the eye to the near vision zone ($p = 0.060$) and in hours per day of PAL usage ($p = 0.023$). In a pattern similar to that for the direct preference comparison, subjects who wore their PAL spectacles for fewer hours per day found adaptation time to be shorter with the test spectacles, whereas those who wore PAL spectacles more than the median number of hours per day adapted more quickly to the control spectacles. In addition, adaptation time was shorter for subjects fit with a medium distance from the eye to the near vision zone (>10 mm and ≤16 mm). Although statistically significant, the magnitude of the difference in adaptation time between test and control spectacles was not more than 2 days on average. Approximately 84.2% of subjects were able to adapt to the control spectacles in 3 days or fewer, as were 85.3% to the test spectacles, most likely due to all subjects being experienced PAL wearers before entering the trial and having no drastic changes in prescription between their habitual spectacles and the study spectacles. All subjects successfully adapted to both test and control spectacles within the 1-week wearing period.

Subjects also expressed greater overall satisfaction with the test spectacles compared with the control spectacles (t-test $p = 0.006$, Fig. 2). Among subjects who wore other types of Zeiss PAL spectacles for their controls, slightly greater overall satisfaction for the control spectacles was reported; with all other brands of control spectacles, the test spectacles ranked higher in overall satisfaction. It is interesting to note that with the test spectacles, most subjects rated their overall satisfaction higher after adapting to their spectacles for 1 week, whereas with control spectacles, after 1 week of wear, many subjects reported a decrease in satisfaction. As expected, adaptation time was a significant factor in subjects' overall satisfaction ratings for both test (t-test, $p < 0.001$) and control spectacles (t-test, $p < 0.001$). There were no significant associations between any demographic factors, pupillary distance or segment height, and any of the subjective outcome measures.

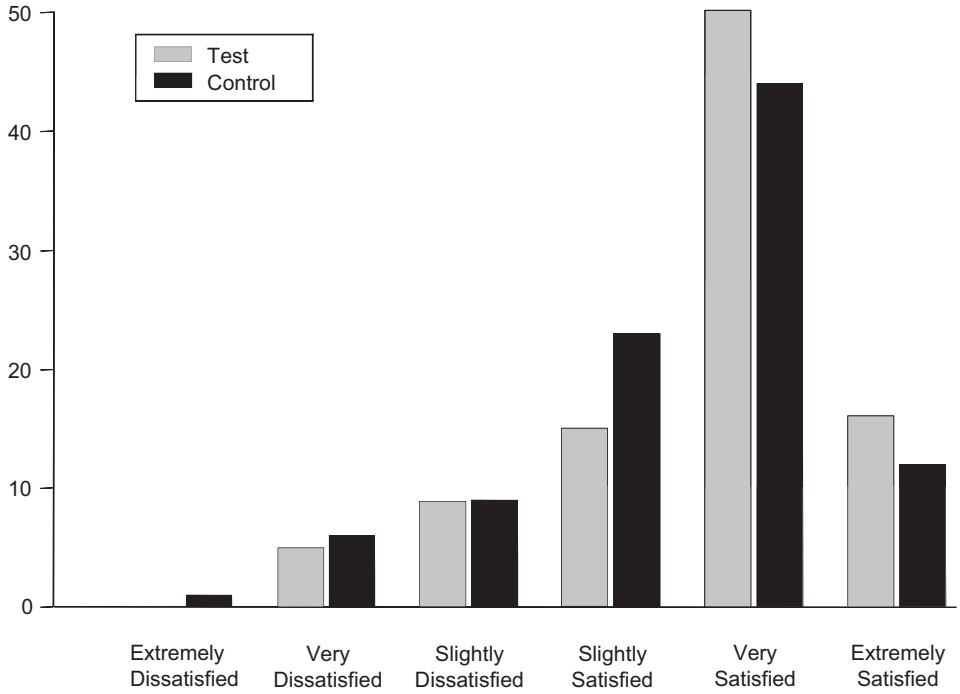

FIGURE 2.

Overall satisfaction. More subjects rated the test spectacles "Very Satisfied" or "Extremely Satisfied" than the controls. No subjects were "Extremely Dissatisfied" with the test spectacles. The majority of subjects were at least "Slightly Satisfied" with both pairs of spectacles.

DISCUSSION

The purpose of our study was to compare objective clinical outcomes and subjective wearing experience with customized, free-form PALs to traditional, non-free-form PALs in an experienced wearing population. To our knowledge, there has not been a double-masked randomized, controlled clinical trial comparing customized free-form progressive lenses to traditional, non-free-form progressive lenses. Many of the problems patients report with adapting to and comfortably using PAL spectacles as their primary presbyopic correction may be due to the optical compromises of mass lens production, and the inability to take into account individual differences in spectacle fit in the design of the lens optics. The advent of individually customized, free-form PAL spectacles may offer the potential to minimize some of the commonly reported problems and to provide better vision and a better overall wearing experience. In this study, we compared customized, free-form to standard, non-free-form PAL spectacles through standard objective clinical vision assessments such as would be performed in a private practice or clinic, and through novel objective assessments specifically designed to detect more subtle differences in visual utility between various types of PAL spectacles. Finally, we compared the two types of PAL spectacles in terms of subjective preferences, adaptation times, and overall satisfaction. Ultimately, the subjective experience of wearing a particular type of PAL spectacle will be the most important factor in translating our findings into clinical practice.

Successful visual performance with PAL spectacles (or lack thereof) is the result of complex interrelationships among the optics of the lenses, the fit of the frame and position of wear, movement of the eyes and head for visual tasks at different viewing distances, as well as individual characteristics of the patient. Even so, we found a high rate of success with both control and test spectacles, probably because of careful fitting by our experienced opticians. Consequently, standard clinical tests of VA, such as are routinely performed in private practice or clinic, did not reveal any clinically important differences between the spectacle types. There was a statistically significant association between spectacle type and low-contrast near acuity. Our model suggests that in the clinical setting, switching full-time PAL wearing patients from some PAL designs to Zeiss Individual may offer improvement in near VA under low-contrast conditions. Although statistically significant, the improvement is approximately half a line on the VA chart, and thus of marginal clinical importance.

The novel vision assessments developed specifically for this PAL trial were more sensitive to subtle performance differences between the test and control spectacles. Low-contrast distance acuity taken at 30° off axis was significantly better (by ~¾ of a line on the chart) with the test spectacles, particularly when spectacles were fit with a short back vertex distance and a small angle of pantoscopic tilt. These results suggest that in the clinical setting, patients who are able to comfortably wear Zeiss Individuals with short back vertex distances and minimal frame tilt can expect significantly better off-axis distance vision under low-contrast conditions. It must be noted that this significant difference was apparent when the chart was viewed off axis to the right side only. Although technicians monitored the subjects to ensure that they maintained a straight forward head position and moved only their eyes to view the chart, it was not possible to completely immobilize the subjects in the head positioning apparatus. It is possible that some bias was introduced by a slightly greater ability to turn the head by a few millimeters to one side but not the other, which was not readily apparent to the technicians. A bite bar would improve immobili-

zation but, obviously, make verbal reading of the chart letters impossible. We are currently investigating other potential ways to improve the head positioning apparatus. There is some evidence that such a left-right asymmetry could also arise from an attentional or reading direction bias, or the cerebral asymmetry of language processing.[11]

The most obvious difference between the test and control spectacles in objective measurements was in the width of the undistorted visual field when viewing through the reading (near vision) zone of the spectacles. Immediately after dispensing, subjects found little difference between the two pairs. However, after 1 week of wear, when subjects were for the most part fully adapted and comfortable with the new pair, the test spectacles provided a wider undistorted reading area, particularly among subjects with fewer years of PAL wear and fit with low segment height. Fewer years of PAL wear includes mainly younger subjects with lower add power, because of their still retaining some degree of accommodative ability. The improvement with the test lenses was greatest for smaller segment heights, probably because it is more strenuous and less comfortable for subjects to down gaze (for example) 30 vs. 16 mm, and then scan their eyes to the right and left.

Differences between test and control spectacles were far more apparent in the subjective responses. As with the objective tests, the significant differences became apparent after subjects had adapted to the spectacles and wore them for 1 week. Subjects preferred the test lenses for distance vision, active vision, transitional, and midrange vision, as well as overall. It might be possible that there was a stronger preference after the week of wear because the subjects were able to discern differences in active, transitional, and midrange vision, which would not have been immediately apparent until subjects used their PALs for everyday activities, as opposed to the limited conditions experienced on dispensing in our laboratory.

Subjects who had >1.5 D of cylinder in their prescriptions, and who did not wear Zeiss brand controls, particularly preferred the test spectacles. For astigmatic subjects who wore either GT2 or Gradal Top for their controls, the preference for the test lenses was only greater for those who wore their PALs for relatively few hours per day and were fit with medium back vertex distances. In contrast, when compared with other brands of control spectacles, the test spectacles were significantly preferred for all back vertex distances and wearing times. Similarly, when each pair of spectacles was rated on a continuous (0 to 100) scale, the test spectacles rated significantly higher than other brands of control spectacles but not when the controls were other models of Zeiss PALs. This might appear to suggest that subjects prefer Zeiss brands because of the quality of the optics in general, and that free-form machining and optical customization do not improve the Zeiss Individual over its other PAL models. However, we do not believe this to be the case, because we have found that back vertex distance and pantoscopic tilt have significant effects on several of our objective and subjective outcomes, and these are fundamental parameters in the optical customization of the individual lenses. It is thus still open to speculation as to why the individual was preferred to other control spectacles but not to the Zeiss brand controls for some subjects in this study.

It is interesting to note that we found very little objective difference in the performance of the test and control spectacles, and yet there was a clear preference for the test spectacles, particularly for astigmatic subjects fit with short-to-medium back vertex distances. In particular, it was surprising that the most obvious objective difference was the greater horizontal extent of undistorted near vision, and yet near vision was the only category in which subjects did not express a preference for the test spectacles. It may be that although the test spectacles performed better for near vision under the highly controlled conditions in our laboratory, subjects did not have a clear preference for one pair or the other for reading or other near work they did under more natural, day-to-day conditions during their week of wear outside the laboratory.

Although subjects adapted significantly more quickly to the test spectacles, the actual difference in adaptation time between the two was on the order of a few days at most, and nearly all subjects adapted to both pairs of spectacles within 2 to 4 days. This result is not surprising in a group of experienced PAL wearers. To determine whether it is truly easier to adapt to the test spectacles, it would be more informative to study a group of neophyte PAL wearers. In this study, we chose to examine experienced PAL wearers because, we knew they would be familiar with how to use PAL spectacles for a variety of different visual tasks and how to transition between visual distances, and that they would be able to adapt to the new lenses quickly, and after 1 week of wear be able to provide fully practiced objective performance and thoughtful, experienced subjective impressions.

In conclusion, we have found that PAL spectacle wear can be improved for many subjects with the Zeiss Individual base design, optically customized for the prescription, frame size, and fitting parameters, combined with free-form manufacturing, to provide each patient with spectacles tailored to his or her specific characteristics. We did not find any important objective differences between customized free-form PALs and standard non-free-form PALs in standard clinical vision assessments. It may be that such objective performance differences do not exist. However, it may be that standard clinical tests are not sufficiently refined to detect subtle performance differences. We did find that it is possible to design vision tests to detect differences in objective performance that are specific to the visual utility of PAL spectacles. Without the more refined objective assessments, the clinician must rely almost entirely on the patient's subjective responses to achieve the optimum wearing experience with PAL spectacles.

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